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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,007	11/28/2000	James L. Kimk	1416.30US01	7252

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EXAMINER

STAICOVICI, STEFAN

ART UNIT PAPER NUMBER

1732

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,007	KURK ET AL.	
	Examiner	Art Unit	
	Stefan Staicovici	1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11,29-35 and 37-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4-11,29-35 and 37 is/are allowed.
- 6) ☐ Claim(s) 38,41-43 and 47-50 is/are rejected.
- 7) ☒ Claim(s) 39,40 and 44-46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed May 24, 2004 has been entered. Claims 1, 29 and 38 have been amended. Claims 3, 12-28 and 36 have been canceled. No new claims have been added. Claims 1-2, 4-11, 29-35, 37-50 are pending in the instant application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 38-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 38, the limitations of a "*radius of curvature*" (emphasis added) being such as to "accommodate a *thickness of polymer composition* on said contoured surface section and said adjacent region of the end surface determined by the *wetting property* of the contoured section surface section and the end surface adjacent region, and by the *viscosity* of the polymer composition" (emphasis added) is indefinite because infinite combinations exist of a polymer viscosity and mold wetting properties that would result in the same thickness, hence the thus defined radius of curvature is not defined by an upper or lower limit.

Claims 39-50 are rejected as dependent claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 38, 41-43, 47 and 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen *et al.* (US Patent No. 5,376,113) in view of Moe *et al.* (US Patent No. 6,174,331 B1) and in further view of Stockum (US Patent No. 4,135,867) and Dreibelbis *et al.* (US Patent No. 5,728,340).

Jansen *et al.* ('113) teach the basic claimed mandrel for making a heart valve (valve prostheses), said mandrel (7) having a plurality of ridges containing therebetween contoured surfaces (5) for forming polymer leaflets of said heart valve (valve prostheses) and further including an edge separating a top flat surface (8) from said contoured surfaces (5), said edge corresponding to free edges of said heart valve (valve prostheses) (see Figure 1).

Regarding claims 38 and 50, Jansen *et al.* ('113) do not teach a dip molding mandrel having a curved edge (radius of curvature). Moe *et al.* ('331) teach a heart valve obtained by dip molding, said heart valve having polymer leaflets which exhibit a radius of curvature and an increased thickness at the edge (see col. 3, lines 50-60; col. 6, lines 31-51 and Figure 6A). Further, it should be noted that it is well known that in a dip molding process, as evidenced by Stockum ('867), a radius of curvature on the mandrel provides for improved releasability of the molded article (see Abstract). It should be noted that the teachings of Stockum ('867) were

employed to show that it is well known that in a dip molding process a radius of curvature on the mandrel provides for improved releasability of the molded article.

Further regarding claims 38 and 50, although Jansen *et al.* ('113) in view of Moe *et al.* ('331) and in further view of Stockum ('867) teach a dipping mold, Jansen *et al.* ('113) does not teach that the radius of curvature of the edge is determined by the polymer viscosity and the wetting property of the mandrel. However, it is well known in the art that in a dipping process, the film thickness retained on the mold is determined by the wetting properties of the mold and the polymer viscosity as evidenced by Dreibelbis *et al.* ('340) who teach that for a given wetting condition the viscosity is preferably within a determined range in order for the dipping process to function (see col. 3, lines 30-40). Therefore, it would have been obvious for one of ordinary skill in the art to have determined an optimum resin viscosity for a given wetting condition as taught by Dreibelbis *et al.* ('340) for the mandrel of Jansen *et al.* ('113) in view of Moe *et al.* ('331) and in further view of Stockum ('867) because, Dreibelbis *et al.* ('340) specifically teach that for a given wetting condition the viscosity is preferably within a determined range in order for the dipping process to function and also because it is well known that a film thickness retained by a mandrel in a dipping process is determined by the resin viscosity and wetting properties of the mandrel.

In regard to claims 41-43, Figure 1 of Jansen *et al.* ('113) teach that the angle between the top surface (8) and the contoured surfaces (5) is no larger than 90 degrees.

Specifically regarding claim 47, Figure 1 of Jansen *et al.* ('113) teach a male mandrel.

Regarding claims 49 and 50, Jansen *et al.* ('113) do not teach a dip molding mandrel having a protruding portion away from the edge. Moe *et al.* ('331) teach a heart valve obtained by dip molding, said heart valve having polymer leaflets which exhibit an increased thickness at the edge (see col. 3, lines 50-60 and col. 6, lines 31-51). It is submitted that a dip mold used to make such a configuration includes a protruding portion away from the edge in order to increase the thickness of the edge, hence it is submitted that the dip mold (mandrel) of Moe *et al.* ('331) includes a protruding portion away from the edge. Therefore, it would have been obvious for one of ordinary skill in the art to have provided a protruding portion away from the edge as taught by Moe *et al.* ('331) in the dip mold of Jansen *et al.* ('113) in view of Stockum ('867) and Dreibelbis *et al.* ('340) because, Moe *et al.* ('331) specifically teach that a thicker leaflet edge provides for an improved heart valve due to an increased strength to compressive loading.

6. Claims 38, 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce *et al.* (US Patent No. 4,364,127) in view of Moe *et al.* (US Patent No. 6,174,331 B1 and in further view of Stockum (US Patent No. 4,135,867) and Dreibelbis *et al.* (US Patent No. 5,728,340).

Pierce *et al.* ('127) teach the basic claimed mandrel for making a heart valve (valve prostheses), said mandrel (32) having a plurality of ridges extending between contoured surfaces which form scallop regions (30) of said heart valve (14) (see Figures 1 and 6). Further, Pierce *et al.* ('127) teach a top surface (40) formed by shims (35) that define a sharp edge separating the contoured surfaces (see Figures 10 and 11).

Regarding claims 38 and 50, Pierce *et al.* ('127) do not teach a dip molding mandrel having a curved edge (radius of curvature). Moe *et al.* ('331) teach a heart valve obtained by dip molding, said heart valve having polymer leaflets which exhibit a radius of curvature and an increased thickness at the edge (see col. 3, lines 50-60; col. 6, lines 31-51 and Figure 6A). Further, it should be noted that it is well known that in a dip molding process, as evidenced by Stockum ('867), a radius of curvature on the mandrel provides for improved releasability of the molded article (see Abstract). It should be noted that the teachings of Stockum ('867) were employed to show that it is well known that in a dip molding process a radius of curvature on the mandrel provides for improved releasability of the molded article.

Further regarding claims 38 and 50, although Pierce *et al.* ('127) in view of Moe *et al.* ('331) and in further view of Stockum ('867) teach a dipping mold, Pierce *et al.* ('127) does not teach that the radius of curvature of the edge is determined by the polymer viscosity and the wetting property of the mandrel. However, it is well known in the art that in a dipping process, the film thickness retained on the mold is determined by the wetting properties of the mold and the polymer viscosity as evidenced by Dreibelbis *et al.* ('340) who teach that for a given wetting condition the viscosity is preferably within a determined range in order for the dipping process to function (see col. 3, lines 30-40). Therefore, it would have been obvious for one of ordinary skill in the art to have determined an optimum resin viscosity for a given wetting condition as taught by Dreibelbis *et al.* ('340) for the mandrel of Pierce *et al.* ('127) in view of Moe *et al.* ('331) and in further view of Stockum ('867) because, Dreibelbis *et al.* ('340) specifically teach that for a given wetting condition the viscosity is preferably within a determined range in order for the

dipping process to function and also because it is well known that a film thickness retained by a mandrel in a dipping process is determined by the resin viscosity and wetting properties of the mandrel.

In regard to claim 48, Pierce *et al.* ('127) teach a female mandrel.

Allowable Subject Matter

7. Claims 1-2, 4-11, 29-35 and 37 are allowed.
8. Claims 39-40 and 44-46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

9. Applicant's arguments filed May 24, 2004 have been considered but are moot in view of the new ground(s) of rejection.

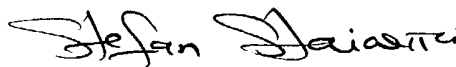
Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stefan Staicovici, Ph.D. whose telephone number is (571) 272-1208. The examiner can normally be reached on Monday-Friday 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Colaianni, can be reached on (571) 272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stefan Staicovici, PhD



Primary Examiner

9/7/04

AU 1732

September 7, 2004